UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

CAROL HASSE-JUNGKURT AND JOE JUNGKURT W/H, Plaintiffs, v. ZIMMER, INC.; ZIMMER HOLDINGS, INC.; ZIMMER TRI-STATE; ZIMMER TRI-STATE d/b/a TRI-STATE ORTHOPEDIC; ZIMMER TRI-STATE d/b/a ZIMMER, INC. Defendants.	Court File No. **COMPLAINT - JURY TRIAL DEMAND**

COMES NOW the Plaintiffs, Carol Hasse-Jungkurt and Joe Jungkurt, by and through their undersigned Counsel, and for their Complaint against the Defendants, allege as follows:

NATURE OF THE CASE

1. This is an action for damages suffered by Carol Hasse-Jungkurt, as a direct and proximate result of Defendants' wrongful conduct in connection with the development, design, manufacture, distribution, and selling of Defendants' knee replacement product, the Zimmer NexGen Legacy Posterior Stabilized High Flex Gender Solutions ("LPS High Flex GSF") femoral component.

2. The Zimmer LPS High Flex GSF femoral component was developed, designed, manufactured, distributed, sold and deliberately promoted by Defendants as an improvement and additional option to the Zimmer NexGen Legacy Posterior Stabilized

("LPS"), another femoral component developed, designed, manufactured, distributed and sold by Defendants. Defendants specifically promoted the LPS High Flex GSF as accommodating "a higher range of motion" and helping patients "maintain an active lifestyle after a total knee replacement."

3. In a total knee arthroplasty, the femoral component options, such as the LPS High Flex GSF or the LPS, are used in conjunction with a patellar component and a tibial component, together, to form the Zimmer NexGen Complete Knee Solution system (all components collectively hereinafter "Zimmer NexGen Knee").

4. Defendants knew or should have known that the LPS High Flex GSF, when used within the Zimmer NexGen Knee, can loosen in patients, such as Plaintiff Carol Hasse-Jungkurt, causing personal injury, significant pain, and loss of movement, and that this injury can only be remedied through subsequent revision surgery and/or knee replacement.

5. The LPS High Flex GSF was defectively designed, developed, manufactured and sold because its increased failure rate and risk of revision is unreasonably greater than other knee implants such as the LPS which achieve the same degree of mobility. The LPS High Flex GSF has no clinical benefit over the LPS that compensates in whole or part for the increased risk. Further, Defendants misled health care professionals and the public into believing that the use of the LPS High Flex GSF in the Zimmer NexGen Knee was safe and effective for use in knee replacement surgery; engaged in deceptive, misleading and unconscionable promotional or sales methods to convince health care professionals to utilize the LPS High Flex GSF, even though

Defendants knew or should have known that the LPS High Flex GSF was unreasonably unsafe; and failed to warn health care professionals and the public of the increased risk of failure associated with the LPS High Flex GSF while offering little to no additional benefit over the Zimmer LPS.

PARTIES

6. Plaintiffs Carol Hasse-Jungkurt and Joe Jungkurt are citizens of the Commonwealth of Pennsylvania, and reside in Chester County, Pennsylvania.

7. Defendant Zimmer, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business located in Warsaw, Indiana.

8. Defendant Zimmer Holdings, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business located in Warsaw, Indiana.

9. Defendant Zimmer Tri-State; Zimmer Tri-State d/b/a Tri-State Orthopedic; Zimmer Tri-State d/b/a Zimmer, Inc. (hereafter collectively "Zimmer Tri-State") is a division of Zimmer, Inc. organized and existing under the laws of New Jersey with its principal place of business in Mount Laurel, New Jersey.

10. At all times material hereto, Defendants developed, designed, tested, manufactured, distributed, marketed, and sold the Zimmer NexGen Knee and the LPS High Flex GSF. Defendants' products, including the Zimmer NexGen Knee and the LPS High Flex GSF are sold throughout the world, including within the Commonwealth of Pennsylvania.

JURISDICTION AND VENUE

11. Jurisdiction over this action exists under 28 U.S.C. §1332, based on diversity of citizenship and an amount in controversy that exceeds $75,000 exclusive of interest and costs.

12. Venue is proper in this district pursuant to 28 U.S.C. §1961, *et seq.*, because a substantial part of the events giving rise to this claim occurred in Pennsylvania and this district.

FACTUAL BACKGROUND
KNEE REPLACEMENT BACKGROUND

13. Total knee arthroplasty (TKA), also called total knee replacement, is a commonly performed medical procedure. The surgery is designed to help relieve pain and improve joint function, generally in people with severe knee degeneration due to arthritis or trauma.

14. The TKA procedure is done by separating the muscles and ligaments around the knee to expose the inside of the joint. The ends of the thigh bone (femur) and the shin bone (tibia) are removed or reduced as is often the underside of the kneecap (patella).

15. About 85 to 90 percent of total knee replacements are successful up to ten years.

16. Mechanical loosening means that the attachment between the artificial knee and the bone has become loose.

17. Loosening can occur with any component of the artificial knee: the femoral, the tibial or the patellar component.

18. Loosening of an artificial knee can be visualized and diagnosed using radiographic imaging. Images of a loose knee joint are one or more radiolucent lines around the contours of the artificial knee joint.

19. A loose artificial knee causes pain and wearing away of the bone. A loose artificial knee can involve a severe psychical burden for the patient and severely restrict the patient's daily activities.

20. Once the individual loses function of the knee or the pain becomes unbearable, another operation can be required to revise the knee replacement. A loose, painful artificial knee can usually, but not always, be replaced.

21. The purpose of knee revision surgery is to remove a failed knee implant and replace it with a new one.

22. Upon information and belief, in an operation revising a total knee failure due to loosening, the most significant problem is the reconstruction of the severe bone loss caused by the failed total knee prosthesis. The bone loss makes it difficult to restore the stability in the revised total knee.

23. Upon information and belief, the success rate of a revision operation is lower than the initial total knee replacement and the risks and complications are higher. The range of motion in the knee after revision surgery may decrease and the walking capacity may be also diminished. The rate of an artificial knee replacement loosening is higher after revision surgery than in primary knee replacement surgery.

ZIMMER NEXGEN KNEE FACTS

24. Zimmer was founded in 1927, and purports to be a worldwide leader in the design and manufacture of orthopaedic reconstructive, spinal and trauma devices, dental implants, and related orthopaedic surgical products.

25. In 1995 Zimmer received 510K approval from the U.S. Food and Drug Administration ("FDA") for its NexGen Complete Knee Solution system.

26. Thereafter, in 1999 Zimmer received FDA 510K approval of its first LPS high flex femoral component design for its Zimmer NexGen Knee line, whereby the maximum active flexion angle was increased from 120 degrees to 155 degrees.

27. In 2006 Zimmer received FDA 510K approval for its NexGen Knee Gender Solutions Female ("GSF") femoral components. The NexGen Knee GSF Femoral Components include both LPS-Flex GSF and CR-Flex GSF versions and are part of the Zimmer Flex-series of semiconstrained, nonlinked, condylar knee prostheses that are designed to have a maximum active flexion of 155 degrees.

28. The GSF designation indicates that the design of the femoral component has been modified slightly to address specific anatomic features of the distal femur that can be seen in both male and female patients, but are more typical of a female patient.

29. Zimmer Gender Solutions High Flex femoral components are marketed as specifically designed to "alleviate knee pain, restore mobility, and offer optimal fit and functionality". To achieve these goals, the design of the Gender Solutions High-Flex femoral components is slightly altered to accommodate the distinctive characteristics typically seen with a woman's knee.

30. In 2007 the FDA granted 510K approval to the porous version of the LPS High Flex GSF which contained a fiber metal pad and was indicated for uncemented use,

31. The Defendants generally, manufactured, labeled, packaged, distributed, supplied, marketed, advertised, and/or otherwise engaged in all activities that are part and parcel of the sale and distribution of a medical device, and by said activities, caused the Zimmer NexGen Knee and the LPS High Flex GSF to be placed into the stream of commerce throughout the United States.

32. Defendants made, participated in and/or contributed to filings with the FDA in conjunction with the approval process for the Zimmer NexGen Knee and the LPS High Flex GSF.

33. Upon information and belief, Defendants was in control of the design, assembly, manufacture, marketing, distribution, packaging, labeling, processing, supplying, promotion, sales, and the issuance of product warnings and related information with respect to the Zimmer NexGen Knee and the LPS High Flex GSF.

34. Defendants were at all times material hereto subject to the laws of the United States of America, including provisions relating to the FDA, and the rules and regulations thereof, in conjunction with the approval process, labeling, and other after-market activities that pertain to the Zimmer NexGen Knee and the LPS High Flex GSF.

35. At various times material and relevant hereto in the last two decades, Defendants jointly or individually sought approval from the FDA for the sale and marketing of the Zimmer NexGen Knee and the LPS High Flex GSF.

36. In seeking approval for the sale of the LPS High Flex GSF, Defendants represented that it was substantially equivalent to a previously approved, or predicate device and therefore could receive premarket approval under Section 510(k) of the FDA.

37. By claiming substantial equivalence, Defendants knew the LPS High Flex GSF was subject to less testing and scrutiny.

38. The LPS High Flex GSF and the Zimmer NexGen Knee have been widely advertised, marketed and represented by the Defendants as a safe and effective total knee prosthesis.

39. The LPS High Flex GSF was aggressively marketed and promoted to the more active female population, including Plaintiff, requiring knee replacement surgery as the state-of-art knee replacement implant providing greater flexion up to 155 degrees, and providing a better, longer lasting fit for females based on the female anatomy.

ZIMMER NEXGEN KNEE HIGH FLEX PROBLEMS

40. Peer reviewed medical literature comparing the standard LPS-Flex and gender specific LPS-Flex knee prosthetic found no additional clinical benefits from the gender specific LPS-Flex total knee prosthetic over the standard LPS-Flex prosthetic at the time of short term follow-up.

41. In 2007, The Journal of Bone and Joint Surgery (British Edition), published a peer reviewed study by professors at the Seoul National University College of Medicine titled, *High Incidence of Loosening of the Femoral Component in the Legacy Posterior Stabilised-Flex Total Knee Replacement.* The study showed that 38% of the implanted

LPS high flex knees were loose shortly after 2 years post implant. From the group of patients with loose knees, over half (56%) had their knee revised due to pain.

42. A 2005 study published in the Journal of Bone and Joint Surgery by Young-Hoo Kim titled, *Range of Motion of Standard and High-Flexion Posterior Stabilized Total Knee Prostheses*, showed no statistical significance between the degree of flexion in the group with the LPS and the group with the LPS-Flex. After two years the mean range of motion in the LPS group was 136 degrees and the LPS-Flex group was 139 degrees.

43. From the time that Defendants first began selling the Zimmer NexGen Knee in the United States, the product labeling and product information for the Zimmer NexGen Knee failed to contain adequate information, instructions, and warnings concerning implantation of the product and the increased risks that the Zimmer NexGen Knee, including the LPS High Flex GSF can prematurely loosen in patients.

44. Despite its knowledge of the serious injuries associated with use of the LPS High Flex GSF and the Zimmer NexGen Knee, Defendants engaged in a marketing and advertising program which as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of the LPS High Flex GSF and the Zimmer NexGen Knee were safe effective.

45. Upon information and belief, Defendants downplayed and understated the health hazards and risks associated with the use of the LPS High Flex GSF and the Zimmer NexGen Knee and through promotional literature as well as sales visits to orthopaedic surgeons, deceived doctors and potential users of the LPS High Flex GSF

and the Zimmer NexGen Knee by relaying positive information, while concealing the nature and extent of known adverse and serious health effects.

46. Upon information and belief, Defendants marketed, promoted, advertised, sold and distributed the LPS High Flex GSF when they knew or should have known that it was a defectively designed product because of its increased failure rate and risk of revision is unreasonably greater than other knee implants such as the LPS which achieve the same degree of mobility. The LPS High Flex GSF has no clinical benefit over the LPS that compensates in whole or part for the increased risk.

FACTUAL ALLEGATIONS

47. On August 25, 2008, Plaintiff's physician implanted a Zimmer NexGen Knee system including a LPS High Flex GSF femoral component.

48. The treating physician for Plaintiff, as well as the Plaintiff, were exposed to the aforementioned advertising and marketing campaign directly by the Defendants.

49. Plaintiff Carol Hasse-Jungkurt and Plaintiff's physician, either through direct promotional contact with Sales Representatives of Defendants, through word-of-mouth from other health care providers influenced by Defendants, and/or through promotional materials from Defendants, received the information the Defendants intended that they receive, to-wit: that the LPS High Flex GSF and the Zimmer NexGen Knee were safe and effective for use in TKA procedures.

50. Plaintiff experienced persistent pain and swelling shortly after implant. Plaintiff underwent manipulation of her joint in October 2008. Thereafter, several

aspirations were performed and on each occasion 40 ml of fluid was obtained. All cultures were negative.

51. Due to persistent pain and decreased mobility on or about July 16, 2010 Plaintiff was advised, for the first time, that she may need a revision surgery.

52. On or about October 21, 2010, Plaintiff had a second surgery to revise/replace her previously implanted Zimmer NexGen Knee. Plaintiff's entire artificial knee system was replaced at which time it was discovered that the femoral component had become internally rotated.

53. As a direct and proximate result of the use of the Zimmer NexGen Knee, including the LPS High Flex GSF, Plaintiff suffered, and continues to suffer, serious bodily injury and harm.

54. As a direct and proximate result of the use of the Zimmer NexGen Knee, including the LPS High Flex GSF, Plaintiff incurred, and continues to incur, medical expenses to treat her injuries and condition.

55. At no time material to her use of the Zimmer NexGen Knee was Plaintiff or her physicians told, warned, or given information about the higher risks of loosening in the Zimmer NexGen Knee and the LPS High Flex GSF.

56. Neither plaintiff knew, or should have known, that the Zimmer NexGen knee implant was defective until October 21, 2010 at the earliest.

COUNT I - STRICT LIABILITY
PLAINTIFFS V. DEFENDANTS

57. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

58. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of Zimmer NexGen Knee and the LPS High Flex GSF. Defendants designed, manufactured, marketed, and sold Zimmer NexGen Knee and the LPS High Flex GSF to medical professionals and their patients, knowing they would be implanted for knee replacements.

59. The Zimmer NexGen Knee and the LPS High Flex GSF as designed, manufactured, marketed and sold by Defendants reached Plaintiff without substantial change in its condition and were used by Plaintiff in a reasonably foreseeable and intended manner.

60. The Zimmer NexGen Knee and the LPS High Flex GSF were "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that Zimmer NexGen Knee and the LPS High Flex GSF were in a condition not suitable for their proper and intended use among patients.

61. The Zimmer NexGen Knee and the LPS High Flex GSF were used in the manner for which it was intended, that is, for artificial knee replacement. This use resulted in injury to Plaintiff.

62. Plaintiff was not able to discover, nor could he have discovered through the exercise of reasonable care, the defective nature of the LPS High Flex GSF and the

Zimmer NexGen Knee. Further, in no way could Plaintiff have known that Defendants had designed, developed, and manufactured the LPS High Flex GSF and the Zimmer NexGen Knee in such a way as to increase the risk of harm or injury to the recipients of them.

63. The LPS High Flex GSF and the Zimmer NexGen Knee are defective in design because of their propensity to loosen and cause patients unnecessary pain and repeat surgical procedures requiring revision resulting in additional bone loss.

64. The LPS High Flex GSF and the Zimmer NexGen Knee are defective in design because the increased risk for failure requiring revision surgery is unreasonably greater than other knee implants such as the LPS. The LPS High Flex GSF offers no clinical benefit over the LPS that compensates in whole or part for the increased risk.

65. The LPS High Flex GSF and the Zimmer NexGen Knee are unreasonably dangerous because it was sold to Plaintiff without adequate warnings regarding, *inter alia,* the propensity of the LPS High Flex GSF and the Zimmer NexGen Knee to loosen and cause serious pain and necessitate additional surgery; the post-marketing experience of higher rates of loosening and revision surgery with the LPS High Flex GSF and the Zimmer NexGen Knee; and the probability of suffering loosening and revision surgery.

66. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable at the time Defendants sold Zimmer NexGen Knee and the LPS High Flex GSF to Plaintiff.

67. The LPS High Flex GSF and the Zimmer NexGen are unreasonably dangerous because they were sold to Plaintiff without adequate warnings regarding, *inter alia,* the increased risk of failure of Zimmer NexGen and LPS High Flex GSF Knee resulting in revision surgery which is unreasonably greater than other knee implants such as the LPS. The LPS High Flex GSF offers no clinical benefit over the LPS that compensates in whole or part for the increased risk.

68. Defendants had knowledge and information confirming the defective and dangerous nature of the Zimmer NexGen Knee and the LPS High Flex GSF. Despite this knowledge and information, Defendants failed to adequately and sufficiently warn Plaintiff and his physicians that Zimmer NexGen Knee and the LPS High Flex GSF cause serious permanent injuries including, high failure rate, loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

69. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings of the LPS High Flex GSF and the Zimmer NexGen Knee's, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

70. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff,

with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II - NEGLIGENT FAILURE TO WARN
PLAINTIFFS V. DEFENDANTS

71. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

72. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the LPS High Flex GSF and the Zimmer NexGen Knee and, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, including the Plaintiff, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the LPS High Flex GSF and the Zimmer NexGen Knee.

73. Defendants failed to adequately warn health care professionals and the public, including Plaintiff Carol Hasse-Jungkurt and her prescribing physician, of the true risks of the LPS High Flex GSF and the Zimmer NexGen Knee, including that the LPS High Flex GSF and the Zimmer NexGen Knee could loosen, causing severe pain and

injury, and requiring further treatment, including revision surgery and/or knee replacement.

74. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the LPS High Flex GSF and the Zimmer NexGen Knee. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician, would have used the LPS High Flex GSF and the Zimmer NexGen Knee, or no consumer, including Plaintiff, would have purchased and/or used the LPS High Flex GSF and the Zimmer NexGen Knee.

75. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the LPS High Flex GSF and the Zimmer NexGen Knee. Had they done so, healthcare professionals, including Plaintiff's physician, could have safely and effectively implanted the LPS High Flex GSF and the Zimmer NexGen Knee, without causing serious pain and injury to patients, including Plaintiff.

76. The LPS High Flex GSF and the Zimmer NexGen Knee, which were researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendants knew or should have known that there was reasonable evidence of an association between the Zimmer NexGen Knee and LPS High Flex GSF and implant loosening causing serious injury and pain, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and

continued to aggressively promote the LPS High Flex GSF and the Zimmer NexGen Knee.

77. The LPS High Flex GSF and the Zimmer NexGen Knee, which were researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of the LPS High Flex GSF resulting in revision surgery while knowing that a safer alternative design, the LPS existed. Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote the LPS High Flex knee GSF, even though it provides no clinical benefits over other knee replacement systems such as the LPS and had a higher failure rate than the LPS.

78. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

79. As a direct and proximate result of the conduct of Defendants as aforesaid, Plaintiff suffered serious and permanent non-economic and economic injuries.

80. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn

or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III – NEGLIGENT DESIGN DEFECT
PLAINTIFFS V. DEFENDANTS

81. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

82. Defendants is the researcher, developer, designer, manufacturer, distributor, marketer, promoter, supplier and seller of the LPS High Flex GSF and the Zimmer NexGen Knee, which is defective an unreasonably dangerous to consumers.

83. The LPS High Flex GSF and the Zimmer NexGen Knee are defective in their design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. The LPS High Flex GSF and the Zimmer NexGen Knee are defective in design or formulation in that they lack efficacy and/or they pose a greater likelihood of injury than other knee replacement devices and similar knee replacement devices on the market and are more dangerous than ordinary consumers can reasonably foresee.

84. If the design defect were known at the time of manufacture, a reasonable person would have concluded that the utility of the LPS High Flex GSF and the Zimmer NexGen Knee did not outweigh the risk of marketing a product designed in that manner.

85. The defective condition of the LPS High Flex GSF and the Zimmer NexGen Knee rendered it unreasonably dangerous and/or unreasonably safe, and the LPS High Flex GSF and the Zimmer NexGen Knee were in this defective condition at the time it left the hands of the Defendants. The LPS High Flex GSF and the Zimmer NexGen Knee was expected to and did reach consumers, including Plaintiff Carol Hasse-Jungkurt, without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

86. Plaintiff and her physician were unaware of the significant hazards and defects in the LPS High Flex GSF and the Zimmer NexGen Knee.

87. The LPS High Flex GSF and the Zimmer NexGen Knee was unreasonably dangerous and/or not reasonably safe in that it was more dangerous than would be reasonably contemplated by the ordinary user. During the period that Plaintiff used the LPS High Flex GSF and the Zimmer NexGen Knee, it was being utilized in a manner that was intended by Defendants.

88. At the time Plaintiff received and used the LPS High Flex GSF and the Zimmer NexGen Knee, it was represented to be safe and free from latent defects.

89. Defendants were negligent for designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable uses at the time it left the control of Defendants because of the design defects.

90. Defendants knew or should have known of the danger associated with the use of the LPS High Flex GSF and the Zimmer NexGen Knee, as well as the defective

nature of the LPS High Flex GSF and the Zimmer NexGen Knee, but continued to design, manufacture, sell, distribute, market, promote and/or supply the LPS High Flex GSF and the Zimmer NexGen Knee so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the LPS High Flex GSF and the Zimmer NexGen Knee.

91. As a direct and proximate cause of the design defect and Defendants' misconduct as set forth herein, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries.

92. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV – NEGLIGENCE
PLAINTIFFS V. DEFENDANTS

93. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

94. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of LPS High Flex GSF and the Zimmer NexGen Knee, including a duty to ensure that LPS High Flex GSF and the Zimmer NexGen Knee did not pose a significantly increased risk of bodily injury to its users.

95. Defendants had a duty to exercise reasonable care in the advertising and sale of LPS High Flex GSF and the Zimmer NexGen Knee, including a duty to warn Plaintiff and other consumers, of the dangers associated with the LPS High Flex GSF and the Zimmer NexGen Knee that were known or should have been known to Defendants at the time of the sale of LPS High Flex GSF and the Zimmer NexGen Knee to the Plaintiff.

96. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of LPS High Flex GSF and the Zimmer NexGen Knee because Defendants knew or should have known that LPS High Flex GSF and the Zimmer NexGen Knee had a propensity to cause serious injury, including loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

97. Defendants failed to exercise ordinary care in the labeling of LPS High Flex GSF and the Zimmer NexGen Knee and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiff, regarding the risk of serious injury, including, loosening and revision surgery.

98. Defendants failed to exercise ordinary care in the labeling of LPS High Flex GSF and the Zimmer NexGen Knee and failed to issue adequate pre-marketing or

post-marketing warnings to doctors and the general public, including Plaintiff, regarding the increased risk of failure when compared to the comparable LPS while the LPS High Flex GSF offers no clinical benefit over the LPS that compensates in whole or part for the increased risk.

99. Defendants knew or should have known that Plaintiff could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

100. Defendants breached their duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances.

101. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, labeling, warnings and distribution of LPS High Flex GSF and the Zimmer NexGen Knee, Plaintiff was implanted with LPS High Flex GSF and the Zimmer NexGen Knee and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

102. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn

or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V - BREACH OF EXPRESS WARRANTY
PLAINTIFFS V. DEFENDANTS

103. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

104. Defendants advertised, labeled, marketed and promoted its product, the LPS High Flex GSF and the Zimmer NexGen Knee, representing the quality to health care professionals, the FDA, Plaintiff Carol Hasse-Jungkurt, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the LPS High Flex GSF and the Zimmer NexGen Knee would conform to the representations. More specifically, Defendants represented that the LPS High Flex GSF and the Zimmer NexGen Knee was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, that it was safe and effective to treat Plaintiff's condition, that it provided an improved implant fit, fewer intraoperative adjustments, less soft-tissue irritation and/or was specifically designed to alleviate knee pain, restore mobility, and offer optimal fit and functionality.

105. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the

goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

106. The LPS High Flex GSF and the Zimmer NexGen Knee did not conform to the representations made by Defendants in that the LPS High Flex GSF and the Zimmer NexGen Knee was not safe and effective, was not safe and effective for use by individuals such as Plaintiff, was not safe and effective to treat Plaintiff's condition, did not provide an improved implant fit, did not result in fewer intraoperative adjustments, caused soft-tissue irritation and/or did not alleviate knee pain, restore mobility, or offer optimal fit and functionality.

107. At all relevant times, Plaintiff used the LPS High Flex GSF and the Zimmer NexGen Knee for the purpose and in the manner intended by Defendants.

108. Plaintiff and Plaintiff's physician, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

109. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

110. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of LPS High Flex GSF and the Zimmer NexGen Knee, Plaintiff was implanted with LPS High Flex GSF and the Zimmer NexGen Knee and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are

entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

111. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI - BREACH OF IMPLIED WARRANTY
PLAINTIFFS V. DEFENDANTS

112. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

113. The LPS High Flex GSF and the Zimmer NexGen Knee was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor were the LPS High Flex GSF and the Zimmer NexGen Knee minimally safe for its expected purpose.

114. At all relevant times, Plaintiff used the LPS High Flex GSF and the Zimmer NexGen Knee for the purpose and in the manner intended by Defendants.

115. Plaintiff and Plaintiff's physician, by the use of reasonable care would not have discovered the breached warranty and realized its danger.

116. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

117. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of the LPS High Flex GSF and the Zimmer NexGen Knee, Plaintiff was implanted with the LPS High Flex GSF and the Zimmer NexGen Knee and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

118. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VII - NEGLIGENT MISREPRESENTATION
PLAINTIFFS V. DEFENDANTS

119. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

120. Prior to the Plaintiff receiving the LPS High Flex GSF and the Zimmer NexGen Knee Defendants misrepresented that the LPS High Flex GSF and the Zimmer NexGen Knee was a safe and effective total knee replacement system.

121. Defendants failed to disclose material facts regarding the safety and efficacy of the LPS High Flex GSF and the Zimmer NexGen Knee, including information regarding increased risk of failure, harmful side-effects, increased risk of revision surgery and results of peer reviewed studies showing an increased risk of revision with little to no clinical benefit over the comparable LPS knee implant.

122. Defendants had a duty to provide Plaintiffs, physicians and other consumers with true and accurate information and warnings of any known risks and harmful side effects of the medical device they marketed, distributed and sold.

123. Defendants knew or should have known; based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures associated with the LPS High Flex GSF and the Zimmer NexGen Knee that their representations regarding the LPS High Flex GSF and the Zimmer NexGen Knee were false, and that they had a duty to disclose the dangers associated with the device.

124. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including the Plaintiff, and the medical

community to act in reliance by purchasing the LPS High Flex GSF and the Zimmer NexGen Knee.

125. Plaintiff and the medical community justifiably relied on Defendants representations and nondisclosures by purchasing and using the LPS High Flex GSF and the Zimmer NexGen Knee.

126. Defendants' representations and nondisclosures regarding the safety and efficacy of the LPS High Flex GSF and the Zimmer NexGen Knee was the direct and proximate cause of Plaintiff's injuries.

127. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII - VIOLATION OF CONSUMER PROTECTION LAWS PLAINTIFFS V. DEFENDANTS

128. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

129. Plaintiff purchased and used the LPS High Flex GSF and the Zimmer NexGen Knee primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

130. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

131. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety and effectiveness of the LPS High Flex GSF and the Zimmer NexGen Knee.

132. Defendants uniformly communicated the purported benefits of the LPS High Flex GSF and the Zimmer NexGen Knee while failing to disclose the serious and dangerous side-effects related to the LPS High Flex GSF and the Zimmer NexGen Knee and of the true state of the LPS High Flex GSF and the Zimmer NexGen Knee, regulatory status, its safety, its efficacy, and its true usefulness. Defendants made these representations to physicians, the medical community at large, and to patients and consumers such as Plaintiff in their marketing and advertising.

133. Defendants conduct in connection with the LPS High Flex GSF and the Zimmer NexGen Knee was also impermissible and illegal in that it created a likelihood of

confusion and misunderstanding, because Defendants misleadingly, falsely, and or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy, and advantages of the LPS High Flex GSF and the Zimmer NexGen Knee.

134. As a result of these violations of the consumer protection laws, Plaintiff has incurred and will incur, serious physical injury, pain, suffering, loss of income, loss of opportunity, loss of family and social relationships and medical, hospital and surgical expenses and other expense related to the failure of the LPS High Flex GSF and the Zimmer NexGen Knee implant Plaintiff received and the resulting revision surgery.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IX - LOSS OF CONSORTIUM
PLAINTIFF, JOE JUNGKURT V. DEFENDANTS

135. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

136. Plaintiff, Joe Jungkurt, was at all times relevant hereto the spouse of plaintiff, Carol Hasse-Jungkurt, and as such lives and cohabits with her.

137. For the reasons set forth herein, Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment, and for medications, and will necessarily incur further expenses of a similar nature in the future.

138. For the reasons set forth herein, Plaintiff has been caused, presently and in the future, to suffer the loss of his spouse's companionship, services, society and the ability of the Plaintiff's spouse have in those respects been impaired and depreciated, and the martial association between husband and wife has been altered, and accordingly, the Plaintiff has been caused great mental anguish.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

WHEREFORE, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

1. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all his injuries and damages, both past and present;

2. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of his injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent instability and loss of balance, and pain and suffering.

3. Double or triple damages as allowed by law;

4. Attorneys' fees, expenses, and costs of this action;

5. Punitive damages, in an amount to be determined at trial;

6. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

7. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

Dated: May 5, 2011

Anapol Schwartz Weiss Cohan
Feldman & Smalley, P.C.

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